

REPLY AND AMENDMENT, March 28, 2003
Serial No.: 08/289,290

LISTING OF CLAIMS

1. (Previously amended) A process of treating a human cancer patient comprising providing to a cancer cell in said patient a nucleic acid encoding a radiosensitizing polypeptide operatively linked to a constitutive promoter and contacting said cell with ionizing radiation, whereby the nucleic acid is expressed to produce the radiosensitizing polypeptide and the cancer is treated.
2. (Previously amended) The process of claim 1, wherein the nucleic acid encodes a TNF- α .
3. (Previously amended) The process of claim 1, wherein the radioprotecting factor is MnSOD, IL-1 or IL-2.
- 4-5. (Cancelled)
6. (Previously amended) The process of claim 1, wherein the constitutive promoter is the immediate-early CMV enhancer/promoter, the RSV enhancer/promoter, the SV40 early promoter, the SV40 late enhancer/promoter, the MMSV LTR, the SFFV enhancer/promoter, the EBV origin of replication, the β -actin promoter, or the Egr enhancer/promoter.
7. (Cancelled)

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8. (Previously amended) The process of claim 1,
wherein said nucleic acid is provided by transfection by
liposomes, adenovirus or HSV-1.

9. (Previously amended) The process of claim 8,
wherein the liposome comprises DOTMA, DOTMA/DOPE, or DORIE.

10. (Previously amended) The process of claim 8,
wherein the transfection is by adenovirus infection.

11. (Previously amended) The process of claim 8,
wherein the transfection is by HSV-1 infection.

12. (Previously amended) A process of sensitizing a
cell to the effects of ionizing radiation comprising
transfected the cell with an adenovirus vector construct
comprising a nucleic acid that encodes a cytokine, wherein said
cytokine is synthesized in and secreted from said cell.

13. (Previously amended) The process of claim 12,
wherein the nucleic acid that encodes the cytokine is positioned
under control of a promoter other than an adenovirus promoter.

14. (Previously amended) The process of claim 13,
wherein the promoter is the immediate-early CMV
enhancer/promoter, the RSV enhancer-promoter, the SV40 early
enhancer/promoter, the SV40 late enhancer/promoter, the MMSV LTR, the

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SFFV enhancer/promoter, the EBV origin of replication, the β-actin promoter or the Egr enhancer/promoter.

15-17. (Cancelled)

18. (Previously Amended) A process of radioprotecting a cell from the effects of ionizing radiation comprising:

(a) obtaining a genetic construct comprising a nucleic acid encoding a cell radioprotecting factor operatively linked to a constitutive promoter; and

(b) transfecting a cell with the genetic construct; whereby said radioprotecting factor is expressed and said cell is protected from said effects.

19. (Previously amended) The process of claim 18, wherein the transfecting is by liposomes, adenovirus or HSV-1.

20. (Previously amended) The process of claim 19, wherein the liposome comprises DOTMA, DOTMA/DOPE, or DORIE.

21. (Previously amended) The process of claim 19, wherein the transfection is by adenovirus infection.

22. (Previously amended) The process of claim 19, wherein the transfection is by HSV-1 infection.

23-25 (Cancelled)

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26. (Previously amended) A process of radioprotecting a cell from the effects of ionizing radiation comprising transfecting the cell with an adenovirus vector construct comprising a nucleic acid encoding a radioprotecting factor in a mammalian cell.

27. (Previously amended) The process of claim 26, wherein the nucleic acid is positioned under control of a promoter other than an adenovirus promoter.

28. (Previously amended) The process of claim 27, wherein the promoter is the immediate-early CMV enhancer/promoter, the RSV enhancer/promoter, the SV40 early promoter, the SV40 late enhancer/promoter, the MMSV LTR, the SFFVs enhancer/promoter, the EBV origin of replication, the β -actin promoter or the Egr enhancer/promoter.

29. (Currently amended) A pharmaceutical composition comprising a genetic construct comprising a nucleic acid that encodes a TNF- α operatively linked to a ~~constitutive~~ an Egr-1 promoter dispersed in a pharmacologically acceptable carrier, wherein the genetic construct is packaged within an adenovirus particle.

30. (Cancelled)

31. (Previously amended) A method of expressing a radioprotecting or radiosensitizing factor in a mammal

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comprising administering to the mammal an effective amount of the pharmaceutical composition of claim 29.

32. (Previously amended) The method of claim 30, wherein the administering is by means of an intravenous injection of from 10^8 to 10^{11} virus particles.

33. (Previously amended) The method of claim 31, wherein the mammal is a mouse.

34. (Previously amended) The method of claim 31, wherein the mammal is a human.

35. (Previously amended) A process of inhibiting growth of a tumor comprising the steps of:

(a) delivering to said tumor a therapeutically effective amount of a DNA molecule comprising a constitutive promoter operatively linked to a region encoding a polypeptide having the ability to inhibit growth of a tumor cell, which coding region further is operatively linked to a transcription-terminating region, whereby said polypeptide is expressed; and

(b) exposing said cell to an effective dose of ionizing radiation,
whereby the growth of said tumor is inhibited by said polypeptide and ionizing radiation.

36. (Previously amended) A method of assessing the response of a cell to the constitutive production of

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radiosensitizing or radioprotecting factors following ionizing radiation comprising:

- (a) growing the cell in culture
- (b) transfected the cell with a genetic construct comprising a nucleic acid that encodes the cell radiosensitizing factor or radioprotecting factor operatively linked to a constitutive promoter, whereby said nucleic acid is expressed to produce the radiosensitizing factor or radioprotecting factor;
- (c) exposing the cell to an effective dose of ionizing radiation; and
- (d) assessing the response of the cell.

37. (Previously added) The pharmaceutical composition of claim 29, wherein the adenovirus particle contains a deletion of the E1 region and/or the E3 region of the adenoviral genome.

38. (Previously added) A process of inhibiting growth of a tumor in a host comprising the steps of:

- (a) injecting into the tumor a therapeutically effective amount of the pharmaceutical composition of claim 29, and
- (b) administering to the host an effective dose of ionizing radiation, whereby the growth of the tumor is inhibited by expression of the nucleic acid encoding a TNF- α and the administration of ionizing radiation.

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39. (Previously added) The process of claim 38,
wherein the amount of the pharmaceutical composition is between
 10^8 and 10^{11} plaque forming units.

40. (Previously added; Currently amended) The
process of claim 38, wherein the total dose of ionizing
radiation is between 50 and 70 Gray.

41. (Previously added) The process of claim 35,
wherein the polypeptide is a TNF- α .

42. (Previously added) The process of claim 12,
wherein the cytokine is a TNF- α .